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PRINCIPAL INVESTIGATOR(S): Timothy J. O'Leary, M.D., Ph.D.

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The objective of this study was to determine effectiveness and cost of Papnet-assisted rescreening in identifying cervical abnormalities not identified by manual Pap smear rescreening methods. Papnet-assisted rescreening was performed on using 5478 Pap smears previously identified as "within normal limits" or "benign changes" on both initial screening and random rescreening. Cases in which a diagnostic change was considered were reviewed by a panel of three cytotechnologists and three pathologists to obtain a consensus diagnosis. Follow-up was attempted on all patients for whom this panel believed a diagnosis of "atypical squamous cells of undetermined significance," (ASCUS) "atypical glandular cells of undetermined significance," (AGUS) or "squamous intraepithelial neoplasia" was warranted. Papnet-assisted examination identified 5 cases of ASCUS and 1 case of AGUS which had not been previously diagnosed; no additional squamous intraepithelial lesions were identified in these smears; the patient with a diagnosis of AGUS on the smear was diagnosed as having a low-grade squamous intraepithelial lesion on follow-up smear.A cost of $8564-34084 (depending on the Papnet charge) for each additional ASCUS/AGUS diagnosis, and a cost of $25691-104410 is expected for each case of low grade SIL identified by Papnet-assisted rescreening and not by traditional manual rescreening.

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INTRODUCTION

The Pap smear is recognized as an effective method of reducing deaths and morbidity from cervical cancer, since it enables detection of precancerous lesions that may be effectively treated. Occasionally, however, abnormal cells are missed by the cytotechnologist. As a result, treatment may be unnecessarily delayed. The military population is at relatively high risk for the development of precancerous lesions (squamous intraepithelial lesions). Approximately one to two percent of Pap smears taken in the military population will be reported to have a significant abnormality. Because examination of Pap smears is laborious, automated systems have recently been proposed for screening Pap smears, or for rescreening them after an initial examination by a cytotechnologist. If effective, these systems would improve the detection of abnormalities, and reduce the costs. The objective of the proposed study was to test the effectiveness of one of these devices in detecting abnormalities that were missed when originally screened, and to compare the effectiveness of the device with that of a second, senior cytotechnologist, performing the rescreening using traditional (manual) methods.

BODY

The Armed Forces Institute of Pathology currently examines approximately 40,000 Pap smears per year. These specimens have been submitted for primary diagnosis by military gynecology clinics throughout the world. The slides are screened by a certified cytotechologist; when significant abnormalities are detected the specimens are examined by a pathologist before rendering a final report. As part of the quality assurance program, ten percent of specimens are screened a second time by a second cytotechnologist. Differences between the findings reported from the first and second screenings are used to monitor interlaboratory variation and personnel performance. The results of this rescreening program are recorded and permanently maintained. We utilized 5,478 of the slides that had undergone this rescreening procedure in a test of the Papnet cytology screening system (Neuromedical Systems, Inc. Suffern, New York). This system uses an automated microscope system and a neural network algorithm to identify 128 of the most abnormal (by this system's criteria) fields. These results are then presented to a cytotechnologist on a computer screen. The cytotechnologist then makes the diagnosis based on the images presented on the screen. To compare the two techniques, the following steps were employed.

A. AFIP personnel identified 5,500 cases that underwent rescreen over a two year period. The slides were retrieved, and submitted to Neuromedical Systems.

B. Neuromedical Systems trained AFIP personnel in the use of the Papnet System.

C. Neuromedical Systems utilized the Papnet system to screen the slides. Digitized "most abnormal" fields were transferred to a magnetic tape.

D. A cytotechnologist performed a second rescreening, using images identified by Papnet.

E. Results were analyzed to determine whether the Papnet rescreening yielded better results than manual. In addition, the cost effectiveness of the Papnet rescreening was examined, using time and motion information collected for both manual and Papnet-assisted rescreening.

RESULTS

We completed the Papnet-assisted rescreen and data analysis on 5478 cases. In 3864 of these cases, the Papnet-assisted rescreen was negative; the review was typically accomplished in 1-2 minutes for each of these cases. In 1614 cases Papnet identified fields which triggered a manual rescreen. Manual rescreens took an average of four to five minutes each.

Papnet-assisted manual rescreen yielded an additional five cases which would be identified as ASCUS (atypical squamous cells of undetermined significance) by six reviewers, and one case which would be classified by these reviewers as atypical **glandular cells of undetermined significance (AGUS). In all cases the cells were rare, and in no case was a failure to identify these cells considered to represent a likely litigation risk. Follow-up was obtained on three of the six patients. The patient with a diagnosis of AGUS was demonstrated to have a low grade squamous epithelial lesion (LSIL) on follow-up Pap smear; the two remaining patients have demonstrated no subsequent abnormality.**

Manual screening was found to take approximately 3 times longer than Papnet-assisted rescreening, in those cases in which manual rescreening was not required (approximately 2/3 of cases), yielding an average savings of 2 minutes per case for Papnet-assisted rescreening. A marginal cost for detection of $8564/case for each ASCUS case is estimated from our data. A more cost-effective approach to identification of persons at risk of developing cervical cancer would be more effective primary screening - i.e. performing Pap smears on women who do not currently get them. By targeting higher risk populations, two to three cases of unequivocal SIL and 3-5 cases of ASCUS can be identified for every 100 persons screened; at a cost of $100/screening (including examination and Pap smear) many more cases will be identified as with the Papnet-assisted rescreening.

CONCLUSIONS

Papnet-assisted rescreening identifies a few more cases of ASCUS than does manual rescreening, but at a very high cost. At current costs, Papnet-assisted rescreening is not as cost effective at identifying possibly precancerous lesions as is extension of traditional cervical cancer screening programs.

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PAPNET-ASSISTED RESCREENING OF CERVICAL SMEARS: COST-EFFECTIVENESS IN COMPARISON WITH A 100% MANUAL RESCREENING STRATEGY

Timothy J. O'Leary, M.D., Ph.D.
Miguel Tellado, M.D.
Sally-Beth Buckner, SCT (ASCP)
Izzat S. Ali, CT (ASCP)
Angelica Stevens, CT (ASCP)
Curtis W. Ollayos, M.D.

Department of Cellular Pathology
Armed Forces Institute of Pathology
Washington, DC 20306-6000

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Address correspondence to:

Timothy J. O'Leary, M.D., Ph.D.
Chairman, Department of Cellular Pathology
Armed Forces Institute of Pathology
14th St. and Alaska Avenue, NW
Washington, DC 20306-6000
Phone: 202-782-2560
FAX: 202-782-7643
email: tjo@afip.mil

Abstract

Objective: The objective of this study was to determine the effectiveness and cost of Papnet-assisted rescreening in identifying cervical abnormalities not identified by manual Pap smear rescreening methods.

Design: Papnet-assisted rescreening was performed on using 5478 Pap smears which had previously been identified as "within normal limits" or "benign changes" on both initial screening and random rescreening. Cases in which a diagnostic change was considered were reviewed by a panel of three cytotechnologists and three pathologists to obtain a consensus diagnosis. Follow-up was attempted on all patients for whom this panel believed a diagnosis of "atypical squamous cells of undetermined significance," (ASCUS) "atypical glandular cells of undetermined significance," (AGUS) or "squamous intraepithelial neoplasia" was warranted.

Setting: Pap smears were obtained from gynecology clinics at a large number of Air Force facilities. The Pap smears were obtained on both service members and dependents, and are typical of those obtained in the primary care setting.

Results: The Papnet-assisted examination identified 5 cases of ASCUS and 1 case of AGUS which had not been previously diagnosed; no additional squamous intraepithelial lesions were identified in these smears; the patient with a diagnosis of AGUS on the smear was diagnosed as having a low-grade squamous intraepithelial lesion on follow-up smear.

Conclusions: A cost of $8564-34084 (depending on the Papnet charge) for each additional ASCUS/AGUS diagnosis, and a cost of $25691-104410 is expected for each case of low grade SIL identified by Papnet-assisted rescreening and not by traditional manual rescreening.

INTRODUCTION

Although the Pap smear has contributed to a significant decrease in cervical cancer mortality, conventional cytologic examination misses a significant number of pre-malignant lesions in which diagnostic cells are present on the slide. Among the tools that are available for reducing false negative rates are automatic rescreening devices, that have been approved recently by the United States Food and Drug Administration [1-4].

The cost-effectiveness of automated rescreening devices is likely to depend upon other laboratory costs, the prevalence of significant lesions within the population screened, and the false negative rate of the laboratory. Among the alternatives to machine-assisted rescreening is manual rescreening of slides previously diagnosed as negative. The advantage to manual rescreening is timeliness, and possibly lower costs; the disadvantage is a potentially lower detection rate, particularly if computer-assisted rescreening relies upon features which are not ordinarily appreciated by cytotechnologists.

In this paper we report the results of a study which assessed the effectiveness of a computer-assisted rescreening system (Papnet) in identifying cellular abnormalities in Pap smears which had been previously diagnosed as "within normal limits" or "benign cellular changes" after both primary screening and a second manual rescreening.

MATERIALS AND METHODS

The Armed Forces Institute of Pathology receives and screens approximately 40,000 cases per year from 8-12 Air Force hospitals and clinics located throughout the United States and Japan. Smears are taken from active duty and retired military personnel, and

from eligible wives and daughters. We identified 5478 cases among those diagnosed in 1994 and 1995 which had been interpreted as "within normal limits" or "benign cellular changes" on both primary screening and a 10% random rescreen. These cases were sequential and included smears from women of all ages. Slides were imaged using the Papnet system, and the digitized images of the 128 most "abnormal" regions were reviewed by one of four individuals (three cytotechnologists, one cytopathologist) who had been trained by Neuromedical Systems. Slides deemed appropriate for review, based on the Neuromedical Systems criteria, were manually rescreened for a third time. If the smear was diagnosed as "atypical squamous/glandular cells of undetermined significance" or higher, the case was further reviewed by a "consensus panel" consisting of three pathologists and three cytotechnologists and a consensus opinion achieved.

RESULTS

Of the 5478 cases imaged using the Papnet system, 3864 (71%) were triaged as negative without further microscopic review. Of the remaining 1614 cases selected for microscopic review, 1166 were identified because no definitive endocervical cells were identified within the Papnet images. Microscopic review revealed that 257 (22%) of these cases actually demonstrated endocervical cells elsewhere on the slide (typically the edge), while 909 did not.

The remaining 448 cases which underwent manual review, did so because the reviewer believed, based on the images presented on the Papnet display, that abnormal cells might be present on the smear. In 11 of these cases, the reviewer believed that previously undiagnosed abnormal cells might be present, and the case was further reviewed microscopically by the "consensus panel." Of these eleven cases, five were classified as

Atypical Squamous Cells of Undetermined Significance (ASCUS), and 1 as Atypical Glandular Cells of Undetermined Significance. In no case did observers universally favor either a reactive or a preneoplastic origin for the cells giving rise to the diagnosis. In one case (that reclassified as AGUS), the patient has had two subsequent Pap smears demonstrating low grade squamous intraepithelial neoplasia (LGSIL); two patients reclassified as ASCUS have demonstrated a single "normal" Pap smear subsequent to the slide entered into this investigation. We have not been able to obtain follow-up for the remaining three patients; their clinical course remains unknown.

Manual screening was found to take approximately 3 times longer than Papnet-assisted rescreening, in those cases in which manual rescreening was not required (approximately 2/3 of cases), yielding an average savings of 2 minutes per case for Papnet-assisted rescreening.

DISCUSSION

The clinical utility of a rescreening procedure depends upon both its efficacy and cost. In the present study, we have demonstrated that Papnet-assisted rescreening identifies a small number of abnormal smears (0.11%) that are not identified on manual rescreening. This result is similar to that reported by Ashfaq et al [5], and is substantially lower than that reported by other investigators [6-15]. The differences are readily explained by the study design. Most other studies have been conducted on samples with a relatively high percentage of abnormal specimens, such as known false-negatives [6,7,13,16], cases originally diagnosed as ASCUS [12], slides which had been enriched in "abnormal" diagnoses [8]or cases which had not been previously screened [9]. Our study was conducted on a sample expected to have a particularly low fraction of false negatives - slides which had already

undergone a negative rescreen. In contrast to all the above studies, therefore, ours strictly addressed the question of whether Papnet-assisted rescreening identified abnormal smears which had not been diagnosed as abnormal on the basis of a primary screen plus a manual rescreen.

While the value of detecting high grade, or even low grade squamous intraepithelial lesions is not questioned, the value of ASCUS/AGUS diagnoses in guiding patient treatment has not been established. For this reason, it is difficult to conclude on the basis of our results that there is any clinical value to Papnet-assisted rescreening. Given the low number of additional abnormal cases which we identified using the Papnet system, cost-effectiveness analysis is difficult. For the following analysis, we assume that the Papnet-assisted rescreen might have been expected to identify two additional cases of LSIL (which it did not, but which might be expected on the basis of 6 ASCUS diagnoses and other reports in the literature).

A cost analysis for our laboratory has identified the cytotechnologist cost to be approximately $3.00 per slide screened, a figure also used by Kaminsky et al [17] in their analysis of rescreening strategies. We employ this cost for completely rescreening a slide identified by Papnet. Based on the time analysis above, cytotechnologist cost for initial Papnet examination (i.e. review of stored images) is 1/3 this cost ($1.00); cases for which complete rescreening is mandated by the Papnet results are expected to cost the same amount as any other manual rescreen for cytotechnologist time. The Papnet system charges were $7.50 per slide, for a total cost of Papnet-assisted rescreening of $9.38/slide. This amounts to a $8564 for each additional ASCUS diagnosis, or $25691 for each expected diagnosis of low grade SIL. If the costs quoted in advertisements for the Papnet system ($40.00/case) are used in this analysis, the marginal cost of Papnet over 100% rescreening is $34804 per case of ASCUS, and $104410 per expected case of low grade

SIL identified. These marginal costs are somewhat higher than those estimated by Hutchinson for Papnet-assisted rescreening [18], apparently reflecting the fact that Papnet-assisted rescreening was less effective in our study than assumed by Hutchinson.

Reduction of cervical cancer mortality can be achieved by a number of different approaches [1]. An approach more cost-effective than Papnet-assisted rescreening to identify women at risk of developing cervical cancer would be more effective screening programs - i.e. performing Pap smears on women who do not currently get them. By targeting higher risk populations, two to three cases of unequivocal SIL and 3-5 cases of ASCUS can be identified for every 100 persons screened; at a cost of $100/screening (including examination and Pap smear) at least twice as many additional cases will be identified as with the Papnet-assisted rescreening. Since absence of diagnostic cells in the smear is a more frequent cause of "missed cases" than is screening error [19], and because additional screening errors may occur because of sample thickness, air-drying artifacts and other controllable factors, educational efforts which teach more effective sampling of the cervix are also likely to be more cost-effective than any rescreening strategy, whether manual or automated.

In summary, Papnet-assisted rescreening identifies a few more cases of ASCUS than does manual rescreening, but at a cost which is difficult to justify given its expected efficacy in reducing cervical cancer mortality.

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DISCLAIMER

The views expressed herein are the personal views of the authors and are not to be construed as official, or as representing the views of the Department Of the Army, the Department of the Navy, the Department of the Air Force or the Department of Defense.

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TITLE:	Microbiology and management of chronic maxillary sinusitis [see comments]
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AUTHOR AFFILIATION:	Department of Infectious Diseases, Naval Hospital, Bethesda, Md.
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ABSTRACT: OBJECTIVE: Assessment of the microbiology and management of patients who suffered from chronic maxillary sinusitis was studied retrospectively. DESIGN: Retrospective analysis of microbiology and antimicrobial therapy of 68 patients who underwent the Caldwell-Luc procedure for chronic sinusitis had not received antimicrobials before surgery and whose cultures showed bacterial growth. SETTING: This study was performed at the Naval Hospital in Bethesda, Md. INTERVENTION: Amoxicillin-clavulanic acid was given to 18 patients, amoxicillin or ampicillin to 25, cefaclor to 17, and erythromycin to eight. RESULTS: A total of 183 isolates (123 anaerobic and 60 aerobic) were recovered. Anaerobic organisms only were recovered from 35 (51%), specimens, and aerobic or facultative bacteria only in 12 (18%), and mixed aerobic and anaerobic flora in 21 (31%). Thirty-four aerobic and anaerobic beta-lactamase-producing bacteria were isolated from 28 patients. The 18 patients who received amoxicillin-clavulanic acid had the most rapid and complete response to therapy, none required a change in therapy, and surgical drainage was required in one case. Of 25 patients who received amoxicillin or ampicillin, eight required a change of therapy due to clinical failure (32%), including three who also had surgical drainage. Of 17 that received cefaclor, five had an antibiotic change (29%), one with surgical drainage. Of the eight who were treated with erythromycin, three needed antibiotic change (38%), two with surgical drainage. Resistant organisms were recovered from most of the patients that required therapeutic change. CONCLUSIONS: These findings indicate the major role of aerobic and anaerobic beta-lactamase-producing bacteria organisms in the polymicrobial etiology of chronic maxillary sinusitis and illustrate the superiority of therapy effective against these bacteria.

MAIN MESH SUBJECTS:	Antibiotics/*THERAPEUTIC USE *Drainage Maxillary Sinusitis/EPIDEMIOLOGY/*MICROBIOLOGY/RADIOGRAPHY/ *SURGERY *Premedication
ADDITIONAL MESH SUBJECTS:	Adolescence Adult Aged Aged, 80 and over Chronic Disease Combined Modality Therapy Female Human Male Microbial Sensitivity Tests Middle Age Retrospective Studies Treatment Outcome
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Citation 36 of 390 from 1994-97

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AUTHOR:	Parsons DS; Wald ER
AUTHOR AFFILIATION:	Division of Otolaryngology, University of Missouri School of Medicine, Columbia 65212, USA.
SOURCE:	Otolaryngol Clin North Am 1996 Feb;29(1):11-25
NLM CIT. ID:	96431187
ABSTRACT:	Otitis media and sinusitis are common pediatric diagnoses and share common features that are described in this article. Although the anatomy, physiology, and disease processes are not identical, knowledge of the basic pathophysiology of middle ear disease often enables a clinician to have a useful working understanding of sinus disease. Recognizing these similarities provides a better understanding of their pathophysiology and treatment.
MAIN MESH SUBJECTS:	Otitis Media/*DIAGNOSIS/DRUG THERAPY/ETIOLOGY Sinusitis/*DIAGNOSIS/DRUG THERAPY/ETIOLOGY
ADDITIONAL MESH SUBJECTS:	Antibiotics/THERAPEUTIC USE Child Child, Preschool Dose-Response Relationship, Drug Drug Administration Schedule Female Human Infant Male Respiratory Tract Infections/COMPLICATIONS/DIAGNOSIS/DRUG THERAPY Treatment Outcome
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